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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,122	06/18/2002	Robert Chalifour	14445-504 NATL.	5542
21559	7590	10/04/2005	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,122

Applicant(s)

CHALIFOUR ET AL.

Examiner

Samuel W. Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-8, 20, 21, 32, 37 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) 41 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42 is/are allowed.
- 6) ☒ Claim(s) claims 1-3, 6-7, 20-21, 32, 37, 39 and 40 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Status of the claims

Claims 1-3, 6-8, 20-21, 32, 37 and 39-42 are pending.

The amendment filed 7/11/05 which amends claims 1, 3, 6-8, 20-21, 32 and 37, and cancels claims 4-5, 22, 29, 34-36 and 38, and adds claims 39-42, has been entered. Note that claims 23-28, 30-31 and 33 are canceled by applicants (the amendment filed 11/5/010).

The new claim 41 contains non-elected subject matter, i.e., SEQ ID NOs: 5, 13 and 23 which do not read on the formula I of claim 1; and thus, claim 41 is not drawn to the elected invention. Claim 41 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The new claims 39, 40 and 42 are drawn to the elected invention. Thus, claims 1-3, 6-8, 20-21, 32, 37, 39, 40 and 42 are examined in this Office action.

Note that the grounds of objection and/or rejection not explicitly stated or restated below are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3, 7, 20-21, 32, 39 and 40 are rejected under 35 U.S.C. 102 (e) as being anticipated by Nordstedt, C. et al. (US Pat. No. 6331440).

In Example 5, Nordstedt et al. disclose a peptide compound comprising “KLVFF” which reads on the instant Formula I of claim 1, wherein all amino acid residues are D-forms (see the patent claim 7). The Nordstedt’s disclosure anticipates the instant claims 1 and 3.

In the above Nordstedt’s peptide, “L” (leucine, equivalent to the instant “Xaa2”) is hydrophobic amino acid “Leu” residue, which anticipates the instant claim 2.

The Nordstedt’s peptide “KLVFF” reads on the instant SEQ ID NO:8, which anticipates the instant claim 7.

In Example 5, Nordstedt et al. teach that the peptide compound (composition) is useful for inhibiting amyloidogenesis, and that the peptide is dissolved in a HEPES buffer solution (see column 6, lines 48-52) wherein the buffer is considered to be pharmaceutical acceptable carrier. The Nordstedt et al. teachings anticipate instant claims 20-21 and 32.

Also, Nordstedt et al. teach that the peptide compound is a drug for treatment of Alzheimer disease and other related amyloidosis, which anticipates instant claims 39 and 40.

The applicants’ response to the rejection under 35USC 102

On pages 12-13, the response filed 7/11/05 argues that the amino acid residues of Nordstedt’s peptide are not all in D-form. The applicants’ argument is found to be unpersuasive because on column 8, lines 11-12, Nordstedt et al. teach the D-pentapeptide having “KLVFF”

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sequence, and also teach that this D-form peptide built up of D-amino acids are resistant to proteolytic degradation and beneficial for inhibition of amyloidogenesis in vivo.

Claims 1-3, 6-7, 20-21, 32, 37 and 39-40 are rejected under 35 U.S.C. 102 (e) as being anticipated by Findeis et al. (US Pat. No. 66303567).

In the patent claim 1, Findeis et al. teach an β -amyloid modulator (inhibiting β -amyloid polypeptide aggregation) which consists entirely of D-amino acid residues and of 3-5 residues. Further, in the patent claim 20, Findels et al. teach the β -amyloid modulator compound comprising the formula set forth in claim 20; this formula meets the all structural characteristics of the instant Formula I (note that the "KLVFF" of the patent SEQ ID NO:46 (columns 67-68) reads on the said formula I). The Findeis' patent anticipates instant claims 1-3 and 7.

In the patent claim 118, Findeis et al. teach peptides of SEQ ID NOs: 28 and 30 which both comprise Lys-Leu-Val-Phe-Phe-Ala, and the peptide of SEQ ID NO:32 consisting of Lys-Leu-Val-Phe-Phe-Ala. Further, in the patent claim 135, Findeis et al. teach retro-inverso isomer of Lys-Leu-Val-Phe-Phe-Ala of the claim 118 sequence SEQ ID NO:32, i.e., the D-Ala-D-Phe-D-Phe-D-Val-D-Leu-D-Lys, which anticipates instant claim 6.

In the patent claim 135, Findeis et al. teach pharmaceutical composition comprising the said claim 118 sequence, which anticipates instant claims 20-21 and 32.

In the patent claim 95, Findeis et al. teach that the peptide of SEQ ID NO:28 comprising Lys-Leu-Val-Phe-Phe-Ala which reads on instant SEQ ID NO:3, and in the patent claim 97, Findeis et al. teach that all L-amino acids of SEQ ID NO:28 is substituted with D-amino acids, which anticipates instant claim 37.

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The instant claims 39-40 recite intended use of the claimed composition for treating amyloidosis disorder, e.g., Alzheimer's disease; the intended use has no patentable weight for the claimed composition. Moreover, Findeis et al. teach use of the peptide compound in treating Alzheimer's disease (see column, 29, lines 7-15). The above Findeis et al. teachings therefore anticipate instant claims 39-40.

The applicants' response to the rejection under 35USC 102

On page 14, the response filed 7/11/05 argues that Findeis et al. do not provide any working examples of all D-amino acid containing peptide that fall within scope of the present claims, and thus, response infers that Findeis is a prima facie non-enabling to the present claims. The applicants' argument is found to be unpersuasive because as stated above, Findeis et al. disclose (in the patent claims) all D-amino acid containing peptides which is subject matter of the Findeis' invention supported by the working examples 1-8. The response discusses the prima facie non-enabling issue regarding that working examples provided in the specification referring to US application No. 06/506098 filed 6/20/1983, *Ex parte Singh* 17 USPQ2d 1714 (6/22/1990). The applicants' argument is found to be not persuasive because the Singh's case may be applicable to a patent application under examination but not to an issued patent which is, in general, considered enable.

On pages 14-16, the response discusses the issue regarding a genus and species and asserts that the claimed composition comprising species of peptides is not envisaged from Findeis' extremely broad generic formulas. The applicants' argument is found to be unpersuasive because the said issue is unrelated to the 102 rejection by Findeis' patent, and

because the rejection is not solely based on the formula set forth in claim 20 (see the above statement) but on definitively disclosed peptide sequence, e.g., the Findeis' SEQ ID NOs: 28 and 32.

Claim Rejections - Provisional Rejection, Obviousness Type Double Patenting

Claims 1 and 7 of this application conflict with claim 27 of Application No.09/915092. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 27 of 09915092. This is a provisional obviousness type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 27 of 09915092 discloses a peptide compound comprising "dLys-dLeu-dVal-dPhe-dPhe-dAla-OH (SEQ ID NO:28) which reads on the instant claim 1 formula I. Note that preamble

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“for inhibiting amyloidosis” is an inherent property of the claimed composition; and thus, the 09915092 compound inherently has the property thereof. The claim 27 is an obvious variation of instant claim 1.

The SEQ ID NO:28 sequence reads on the instant SEQ ID NO:3, which is the subject matter of instant claim 7.

Thus, the claims and the instant claims are not patentably distinct from each other.

Note that “10345855” set forth in line 2 of page 14 of the Office action mailed 4/8/05 should be corrected to “09915092”.

Claim 8, which is directed the instant SEQ ID NO:2, are objected to as being dependent upon a rejected base claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-3, 6-8, 20-21, 32, 37, 39 and 40 are not allowed; and claim 42 is free from prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

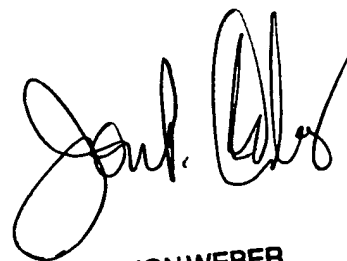
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber, Jon, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.

Art Unit 1653, Examiner

September 21, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER